CTMS Adverse Events Reporting SIG Teleconference Meeting Minutes

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Wednesday, September 17, 2004

3:00 - 4:00 PM EDT

Attendees:

Working group coordinator: Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen Hamilton)

Participants:

Name	Email	Center
Joyce Niland (SIG lead)	jniland@coh.org	City of Hope
Amy Cox	acox@coh.org	City of Hope
Andrea Hwang	ychwang@uci.edu	UC Irvine
Bob Morrell	bmorrell@wfubmc.edu	Wake Forest
Diane Paul	funnylady93@earthlink.net	CARRA
Erin Iturriaga	iturriae@mail.nih.gov	DCP
Hemant Shah	hshah@coh.org	City of Hope
Jennifer Neat	JNeat@coh.org	City of Hope
John Speakman	speakman@biost.mskcc.org	Sloan-Kettering
Rhoda Arzoomanian	rza@medicine.wisc.edu	Wisconsin
Linda Parreco	parrecol@mail.nih.gov	DCP

Agenda

I. Review of Minutes:

September 3, 2004

- II. Updated Proposed AE System High Level Diagram Review (Amy Cox COH)
- III. Review of DCP AE Process Diagram (Amy Cox COH) CTEP and CDUS flow processes have been added to the current AE Process Diagram, which was reviewed at the face-to-face meeting
- IV. CaBIG AE, CTMS-CDUS Survey Summary Review: Updated Results (Dr. Niland and Amy Cox COH)
- V. Reminder: CaBIG CTMS Quarterly In-Person Meeting Location: City of Hope National Medical Center, Duarte, CA

Dates: November 16 – 17, 2004

Agenda Items?

VI. Future Plans

VII. Next Meeting: October 1, 2004

General discussion points raised by participants:

Amy Cox presented the AE System High Level Diagram Review after modifications based on feedback from DCP and from the last SIG teleconference. These included mapping the data fields between the cancer centers' AE system and the caBIG AE system (page 2). This mapping will be based on MedDRA codes (although CTEP is moving away from them) and SNOMED CDEs. CTEP is developing a few classifications that are better mapped to NCI Thesaurus and Metathesaurus and they may be later mapped to SNOMED according to Hemant Shah.

CDUS is beginning to work with NCI to map to CDEs and that may be the common point that may allow the different systems to map to CDEs and to each other (Joyce Niland). The SIG agreed that a table that has the various mappings for the data and allows for flexibility (to accommodate changes in data elements) would be a useful way to address this issue.

The other change to the AE module flow diagram was on page 6 (data mining and the public websites) where the aggregated AE data would be reviewed and approved by a (yet to be determined) review body before it is posted to a public website.

Changes to the Adverse Events reporting module were also made based on the DCP Adverse Events reporting flow processes provided by DCP (and Erin Iturriaga). Several flow processes could be outlined for DCP Adverse Events reporting depending on who the IND holder was. Joyce Niland enquired if it was possible to harmonize the different reporting procedures (for the different IND holders). Erin Iturriaga agreed to examine the flow processes to see if this was possible. Amy Cox is also incorporating flow processes relating to CTEP for triggering AE reporting based on feedback from Ann Setser

An update on the CTMS/CDUS Adverse Events reporting survey was presented. The number of respondents had increased to 18 from 16 and there were 11 institutions who had not responded. In addition, some follow up was necessary for respondents who had not completed the survey entirely. Version 3 of the survey included additional questions based on feedback from NCI on what the current functionality was in existing systems, what features were desirable and if a cancer center had a home grown system, could it be contributed to caBIG

The plan for the upcoming face-to-face meeting was discussed (individual meetings, group meetings, agenda items etc.). The meeting format should allow people to attend all the sessions and not to have to choose between one or the other (Rhoda Arzoomanian). SIG members could send in suggestion for the agenda to Joyce Niland and Scott Finley.

Action items:

Incorporate flow processed from CTEP and review optimal idealized workflow for harmonized unified AE reporting module

Suggest face-to-face meeting format/agenda items